K120377
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JUL 25 2012

510(k) summary

Company name and address : J.MORITA MFG. CORP.
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Fushimi-ku, Kyoto, Japan
Telephone: +81-75-611-2141
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Date of preparation: April 10, 2012

Contact: Yoshihide Okagami
General Manager of Technical Administration

1. NAME OF DEVICE and Intended Use/Indications of Use

Trade or Proprietary Name: AdvErL EVO Er: YAG Laser for Dentistry
Model: MEY-1-A
*Note: The name is referred to as " **MEY-1-A**" hereafter.*

Common Name: Dental medical laser equipment

Usual Name: Medical laser system

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology (21CFR878.4810)

Product Code : GEX

Intended Use : Device is intended for the incision, excision, vaporization, ablation and coagulation of soft tissue in oral and dentistry and for the ablation and vaporization of hard tissue in dentistry.

Predicate devices and Indications of use:

The MEY-1-A is substantially equivalent to both predicate devices of "VERSAWAVE DENTAL ER:YAG LASER SYSTEM (K#041710) " made by HOYA CONBIO and " WATERLASE MD TURBO PLUS MODEL 7200XXX(K#101658)" made by BIOLASE TECHNOLOGY, INC.

The indications of use of the MEY-1-A covers all identical indications of " VERSAWAVE DENTAL ER:YAG LASER SYSTEM (K#041710) " , however, lacks the indications of "Root canal indications / Laser root canal disinfection after endodontic" which is included in the indications of "WATERLASE MD TURBO PLUS MODEL 7200XXX(K#101658) " .

As for details of indications refer to **FOOT NOTE** of this summary..

2. ESTABLISHMENT REGISTRATION NUMBER

Registration No. 2081055
Initial Distributor:
J. MORITA USA, INC.
9 Mason
Irvine, CA 92618
USA
Telephone: 949-581-9600
Facsimile: 949-581-9688

Registration No. 3002807636
Manufacturer:
J. MORITA MFG. CORP.
680 Higashihama Minami-cho
Fushimi-ku, Kyoto
Japan 612-8533
+81-75-611-2141
+81-75-605-2354

3. **DEVICE CLASSIFICATION / CLASSIFICATION PANEL**

Device classification: Class 2 medical devise
21CFR878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology

Laser classification: Class 4 medical laser product
Per 21CFR 1040.10 and per 21CFR 1040.11

Device classification panel: 76 Dental

4. **PERFORMANCE STANDARDS**

We examine the performance of the MEY-1-A by using the international standards ;

IEC 60601-1:2005	Medical electrical equipment Part 1: General requirements for basicsafety and essential performance
IEC 60601-2-22	Medical electrical equipment Part 2: Particular requirements for safety of diagnostic and therapeutic laser equipment
IEC 60825-1	Safety of laser products-Part 1: Equipment classification and requirements
IEC 60601-1-2:2007	Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility -equipments and tests Edition 3)

5. **DEVICE DESCRIPTION and SUBSTANTIAL EQUIVALENCE**

A. DEVICE DESCRIPTION

General Product Information

Equipment is mobile Er:YAG Medical Treatment and Coagulation Laser of model MEY-1-A intended to be used for dental surgery in hospital environment.

Er:YAG Laser emits an infrared beam with a wavelength 2.94 μm which is readily absorbed by water contained by both hard and soft tissues of the human body. As a result, a energy of the laser beam instantly vaporized the water molecules in hard tissues of the tooth causing the tissues to crumble away or resection of the soft tissues of gingival.

B. SUBSTANTIAL EQUIVALENCE

Company's proposal for establishing substantial equivalence of the MEY-1-A by demonstrating Comparison Table where the MEY-1-A is compared with two different predicate devices.

As a result of this comparison, the MEY-1-A has not only the same " intended use and Indications of use", but also has the substantially same " equivalent technical specifications" compared with the predicate device Ⅰ (Versa Wave Dental Er: YAG Laser System K#041710) and the predicate device Ⅱ (WaterLase MD Turbo Plus MODEL 7200XXX : K#101658).

There are some differences in respects of display, power calibration and software, however, these are esteemed to be minor differences since we presume that they use similar existing technology with ours to realize their functions in each design stage, so that such slight difference would not cause substantial impacts to effectiveness or safety problems.

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FOOT NOTE:

Indications for Use Statement

Device Name: AdvErL EVO Er: YAG Laser for Dentistry
Model: MEY-1-A

Indications for Use:
Hard Tissue
General Indications*
• Class I, II, III, IV and V cavity preparation
• Caries removal
• Hard tissue surface roughening or etching
• Enameloplasty, excavation of pits and fissures for placement of sealants
* For use on adult and pediatric patients
Root Canal Hard Tissue Indications
• Tooth preparation to obtain access to root canal
• Root canal preparation including enlargement
• Root canal debridement and cleaning
Bone Surgical Indications
• Cutting, shaving, contouring and resection of oral osseous tissues (bone)
• Osteotomy

Endodontic Surgery (Root Amputation) Indications
• Flap preparation – incision of soft tissue to prepare a flap and expose the bone.
• Cutting bone to prepare a window access to the apex (apices) of the root(s).
• Apicoectomy – amputation of the root end.
• Root end preparation for retrofill amalgam or composite.
• Removal of pathological tissues (i.e., cysts, neoplasm or abscess) and hyperplastic tissues(i.e., granulation tissue) from around the apex.
NOTE: Any tissue growth (i.e., cyst, neoplasm or other lesions) must be submitted to a qualified laboratory for histopathological evaluation.
Laser Periodontal Procedures
• Full thickness flap
• Partial thickness flap
• Split thickness flap
• Laser soft tissue curettage
• Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket
• Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium
• Removal of granulation tissue from bony defects
• Sulcular debridement (removal of diseased, infected, inflamed or necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)
• Osteoplasty and osseous recontouring (removal of bone to correct osseous defects and create physiologic osseous contours)
• Ostectomy (resection of bone to restore bony architecture, resection of bone for grafting,

etc.)
• Osseous crown lengthening
• Removal of subgingival
Soft Tissue Indications including Pulpal Tissues*
Incision, excision, vaporization, ablation and coagulation of oral soft tissues, including:
• Excisional and incisional biopsies
• Exposure of unerupted teeth
• Fibroma removal
• Flap preparation – incision of soft tissue to prepare a flap and expose the bone.
• Flap preparation – incision of soft tissue to prepare a flap and expose unerupted teeth (hard and soft tissue impactions)
• Frenectomy and frenotomy
• Gingival troughing for crown impressions
• Gingivectomy
• Gingivoplasty
• Gingival incision and excision
• Hemostasis and coagulation
• Implant recovery
• Incision and drainage of abscesses
• Incision and drainage of periapical abscesses
• Laser soft tissue curettage of the post-extraction tooth sockets and the periapical area during apical surgery
• Leukoplakia
• Operculectomy
• Oral papillectomies
• Pulpotomy
• Pulp extirpation
• Pulpotomy as an adjunct to root canal therapy
• Reduction of gingival hypertrophy
• Removal of pathological tissues (i.e. cysts, neoplasm or abscess) and hyperplastic tissues (i.e. granulation tissue) from around the apex .
NOTE: Any tissue growth (i.e., cyst, neoplasm or other lesions) must be submitted to a qualified laboratory for histopathological evaluation.
• Root canal debridement and cleaning
• Soft tissue crown lengthening
• Treatment of canker sores, herpe tic and aphthous ulcers of the oral mucosa
• Vestibuloplasty
* For use on adult and pediatric patients

N.B.
1) The abovementioned indications of use of the MEY-1-A is same to all the terms of " VERSAWAVE DENTAL ER:YAG LASER SYSTEM (K#041710)" except " *Removal of subgingival calculus*".
2) On the other hand, the indications of use of the MEY-1-A lacks the indication of "Root canal indications / Laser root canal disinfection after endodontic" which is included in the indications of "WATERLASE MD TURBO PLUS MODEL 7200XXX(K#101658) ".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

J. Morita USA, Incorporated
% Fish & Richardson P.C.
Mr. Keith A. Barritt
1425 K. Street Northwest
Suite 1100
Washington, District of Columbia 20005

JUL 25 2012

Re: K120377
Trade/Device Name: AdvErl EVO ER: YAG laser for Dentistry Model: MEY-1-A
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: July 13, 2012
Received: July 16, 2012

Dear Mr. Barritt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Device
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use statement

510(K) Number : **K120377**

Device Name: AdvErL EVO Er: YAG Laser for Dentistry

Model: MEY-1-A

Indications for Use:

Hard Tissue

General Indications*

- Class I, II, III, IV and V cavity preparation
- Caries removal
- Hard tissue surface roughening or etching
- Enameloplasty, excavation of pits and fissures for placement of sealants

* For use on adult and pediatric patients

Root Canal Hard Tissue Indications

- Tooth preparation to obtain access to root canal
- Root canal preparation including enlargement
- Root canal debridement and cleaning

Bone Surgical Indications

- Cutting, shaving, contouring and resection of oral osseous tissues (bone)
- Osteotomy

Endodontic Surgery (Root Amputation) Indications

- Flap preparation – incision of soft tissue to prepare a flap and expose the bone.
- Cutting bone to prepare a window access to the apex (apices) of the root(s).
- Apicoectomy – amputation of the root end.
- Root end preparation for retrofill amalgam or composite.
- Removal of pathological tissues (i.e., cysts, neoplasm or abscess) and hyperplastic tissues(i.e., granulation tissue) from around the apex.

NOTE: Any tissue growth (i.e., cyst, neoplasm or other lesions) must be submitted to a qualified laboratory for histopathological evaluation.

Laser Periodontal Procedures

- Full thickness flap
- Partial thickness flap
- Split thickness flap
- Laser soft tissue curettage
- Laser removal of diseased, infected, inflamed and necrosed soft tissue within the

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periodontal pocket

• Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium

• Removal of granulation tissue from bony defects

• Sulcular debridement (removal of diseased, infected, inflamed or necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)

• Osteoplasty and osseous recontouring (removal of bone to correct osseous defects and create physiological osseous contours)

• Ostectomy (resection of bone to restore bony architecture, resection of bone for grafting, etc.)

• Osseous crown lengthening

• Removal of subgingival calculus

Soft Tissue Indications including Pulpal Tissues*

Incision, excision, vaporization, ablation and coagulation of oral soft tissues, including:

• Excisional and incisional biopsies

• Exposure of unerupted teeth

• Fibroma removal

• Flap preparation – incision of soft tissue to prepare a flap and expose the bone.

• Flap preparation – incision of soft tissue to prepare a flap and expose unerupted teeth (hard and soft tissue impactions)

• Frenectomy and frenotomy

• Gingival troughing for crown impressions

• Gingivectomy

• Gingivoplasty

• Gingival incision and excision

• Hemostasis and coagulation

• Implant recovery

• Incision and drainage of abscesses

• Incision and drainage of periapical abscesses

• Laser soft tissue curettage of the post-extraction tooth sockets and the periapical area during apical surgery

• Leukoplakia

• Operculectomy

• Oral papillectomies

• Pulpotomy

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• Pulp extirpation

• Pulpotomy as an adjunct to root canal therapy

• Reduction of gingival hypertrophy

• Removal of pathological tissues (i.e. cysts, neoplasm or abscess) and hyperplastic tissues (i.e. granulation tissue) from around the apex.

NOTE: Any tissue growth (i.e., cyst, neoplasm or other lesions) must be submitted to a qualified laboratory for histopathological evaluation.

• Root canal debridement and cleaning

• Soft tissue crown lengthening

• Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa

• Vestibuloplasty

* For use on adult and pediatric patients

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Prescription Use__X___ AND/OR Over-The-Counter Use _____
(Part21CFR801 Subpart D) (Part21CFR807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation(ODE)

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